General

Guideline Title

Guidelines on the management of valvular heart disease (version 2012).

Bibliographic Source(s)

Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (, European Association for Cardio-Thoracic Surgery (EACTS), Vahanian A, Alfieri O, Andreotti F, Antunes MJ, Baron-Esquivias G, Baumgartner H, Borger MA, Carrel TP, De Bonis M, Evangelista A, Falk V, Iung B, Lancellotti P, Pierard L, Price S, Schafers HJ, Schuler G, Stepinska J, Swedberg K, Takkenberg J, Von Oppell UO, Windecker S, Zamorano JL, Zembala M. Guidelines on the management of valvular heart disease (version 2012). Eur Heart J. 2012 Oct;33(19):2451-96. PubMed

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Vahanian A, Baumgartner H, Bax J, Butchart E, Dion R, Filippatos G, Flachskampf F, Hall R, Iung B, Kasprzak J, Nataf P, Tornos P, Torracca L, Wenink A, Priori SG, Blanc JJ, Budaj A, Camm J, Dean V, Deckers J, Dickstein K, Lekakis J, McGregor K, Metra M, Morais J, Osterspey A, Tamargo J, Zamorano JL, Zamorano JL, Angelini A, Antunes M, Fernandez MA, Gohlke-Baerwolf C, Habib G, McMurray J, Otto C, Pierard L, Pomar JL, Prendergast B, Rosenhek R, Uva MS, Tamargo J. Guidelines on the management of valvular heart disease: The Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology. Eur Heart J 2007 Jan;28(2):230-68.

Recommendations

Major Recommendations

Definitions for the recommendation classes (I-III) and levels of evidence (A-C) are given at the end of the "Major Recommendations" field.

General Comments

Invasive Investigations

Management of Coronary Artery Disease in Patients with Valvular Heart Disease (adapted from the Task Force on Myocardial Revascularization of the European Society of Cardiology [ESC] et al., 2010)

Diagnosis of Coronary Artery Disease

Coronary angiography* is recommended before valve surgery in patients with severe valvular heart disease and any of the following:

- History of coronary artery disease

- Suspected myocardial ischaemia (chest pain, abnormal non-invasive testing)
- Left ventricular systolic dysfunction
- In men aged over 40 years and postmenopausal women
- ≥1 cardiovascular risk factor

(Class of recommendation I, level of evidence C)

Coronary angiography is recommended in the evaluation of secondary mitral regurgitation. (Class of recommendation I, level of evidence C)

Indications for Myocardial Revascularization

Coronary artery bypass grafting (CABG) is recommended in patients with a primary indication for aortic/mitral valve surgery and coronary artery diameter stenosis ≥70%.** (Class of recommendation I, level of evidence C)

CABG should be considered in patients with a primary indication for aortic/mitral valve surgery and coronary artery diameter stenosis ≥50%–70%. (Class of recommendation IIa, level of evidence C)

*Multi-slice computed tomography may be used to exclude coronary artery disease in patients who are at low risk of atherosclerosis.

**≥50% can be considered for left main stenosis.

Aortic Regurgitation (AR)

Indications for Surgery

Indications for Surgery in Severe Aortic Regurgitation and Aortic Root Disease (whatever the severity of aortic regurgitation)

Indications for Surgery in Severe Aortic Regurgitation

Surgery is indicated in symptomatic patients. (Class of recommendation I, level of evidence B) (Dujardin et al., 1999).

Surgery is indicated in asymptomatic patients with resting left ventricular ejection fraction (LVEF) ≤50%. (Class of recommendation I, level of evidence B) (Chaliki et al., 2002)

Surgery is indicated in patients undergoing CABG or surgery of ascending aorta, or on another valve. (Class of recommendation I, level of evidence C)

Surgery should be considered in asymptomatic patients with resting ejection fraction (EF) >50% with severe LV dilatation: left ventricular end-diastolic diameter (LVEDD) >70 mm, or left ventricular end-systolic diameter (LVESD) >50 mm or LVESD >25 mm/m^2 body surface area (BSA).* (Class of recommendation IIa, level of evidence C)

Indications for Surgery in Aortic Root Disease (whatever the severity of AR)

Surgery is indicated in patients who have aortic root disease with maximal ascending aortic diameter** ≥50 mm for patients with Marfan syndrome. (Class of recommendation I, level of evidence C)

Surgery should be considered in patients who have aortic root disease with maximal ascending aortic diameter:

- ≥45 mm for patients with Marfan syndrome with risk factors†
- ≥50 mm for patients with bicuspid valve with risk factors‡
- ≥55 mm for other patients

(Class of recommendation IIa, level of evidence C)

*Changes in sequential measurements should be taken into account.

**Decision should also take into account the shape of the different parts of the aorta. Lower thresholds can be used for combining surgery on the ascending aorta for patients who have an indication for surgery on the aortic valve.

†Family history of aortic dissection and/or aortic size increase >2 mm/year (on repeated measurements using the same imaging technique, measured at the same aorta level with side-by-side comparison and confirmed by another technique), severe AR or mitral regurgitation, desire of pregnancy.

‡Coarctation of the aorta, systemic hypertension, family history of dissection or increase in aortic diameter >2 mm/year (on repeated measurements using the same imaging technique, measured at the same aorta level with side-by-side comparison and confirmed by another technique).

Aortic Stenosis (AS)

Indications for Intervention

Indications for Aortic Valve Replacement (AVR) in Aortic Stenosis

AVR is indicated in patients with severe AS and any symptoms related to AS. (Class of recommendation I, level of evidence B) (Vahanian et al., 2009; Rosenhek et al., 2000; Brown et al., 2009)

AVR is indicated in patients with severe AS undergoing CABG, surgery of the ascending aorta or another valve. (Class of recommendation I, level of evidence C)

AVR is indicated in asymptomatic patients with severe AS and systolic LV dysfunction (LVEF <50%) not due to another cause. (Class of recommendation I, level of evidence C)

AVR is indicated in asymptomatic patients with severe AS and abnormal exercise test showing symptoms on exercise clearly related to AS. (Class of recommendation I, level of evidence C)

AVR should be considered in high risk patients with severe symptomatic AS who are suitable for transcatheter aortic valve implantation (TAVI), but in whom surgery is favoured by a 'heart team' based on the individual risk profile and anatomic suitability. (Class of recommendation IIa, level of evidence B) (Smith et al., 2011)

AVR should be considered in asymptomatic patients with severe AS and abnormal exercise test showing fall in blood pressure below baseline. (Class of recommendation IIa, level of evidence C)

AVR should be considered in patients with moderate AS* undergoing CABG, surgery of the ascending aorta or another valve. (Class of recommendation IIa, level of evidence C)

AVR should be considered in symptomatic patients with low flow, low gradient (<40 mmHg) AS with normal EF only after careful confirmation of severe AS.** (Class of recommendation IIa, level of evidence C)

AVR should be considered in symptomatic patients with severe AS, low flow, low gradient with reduced EF, and evidence of flow reserve (also termed contractile reserve). (Class of recommendation IIa, level of evidence C)

AVR should be considered in asymptomatic patients, with normal EF and none of the above-mentioned exercise test abnormalities, if the surgical risk is low, and one or more of the following findings is present:

- Very severe AS defined by a peak transvalvular velocity >5.5 m/s *or*
- Severe valve calcification and a rate of peak transvalvular velocity progression ≥0.3 m/s per year

(Class of recommendation IIa, level of evidence C)

AVR may be considered in symptomatic patients with severe AS low flow, low gradient, and LV dysfunction without flow reserve (also termed contractile reserve). (Class of recommendation IIb, level of evidence C)

AVR may be considered in asymptomatic patients with severe AS, normal EF and none of the above-mentioned exercise test abnormalities, if surgical risk is low, and one or more of the following findings is present:

- Markedly elevated natriuretic peptide levels confirmed by repeated measurements and without other explanations
- Increase of mean pressure gradient with exercise by >20 mmHg
- Excessive LV hypertrophy in the absence of hypertension

(Class of recommendation IIb, level of evidence C)

*Moderate AS is defined as valve area 1.0–1.5 cm^2 (0.6 cm^2/m^2 to 0.9 cm^2/m^2 BSA) or mean aortic gradient 25–40 mmHg in the presence of normal flow conditions. However, clinical judgement is required.

**In patients with a small valve area but low gradient despite preserved LVEF, explanations for this finding (other than the presence of severe AS) are frequent and must be carefully excluded (see the original guideline document).

Recommendations for the Use of Transcatheter Aortic Valve Implantation

TAVI should only be undertaken with a multidisciplinary 'heart team' including cardiologists and cardiac surgeons and other specialists if necessary. (Class of recommendation I, level of evidence C)

TAVI should only be performed in hospitals with cardiac surgery on-site. (Class of recommendation I, level of evidence C)

TAVI is indicated in patients with severe symptomatic AS who are not suitable for AVR as assessed by a 'heart team' and who are likely to gain improvement in their quality of life and to have a life expectancy of more than 1 year after consideration of their comorbidities. (Class of recommendation I, level of evidence B) (Leon et al., 2010)

TAVI should be considered in high-risk patients with severe symptomatic AS who may still be suitable for surgery, but in whom TAVI is favoured by a 'heart team' based on the individual risk profile and anatomic suitability. (Class of recommendation IIa, level of evidence B) (Smith et al., 2011)

Mitral Regurgitation (MR)

Indications for Surgery in Severe Primary Mitral Regurgitation

Mitral valve repair should be the preferred technique when it is expected to be durable. (Class of recommendation I, level of evidence C)

Surgery is indicated in symptomatic patients with LVEF >30% and LVESD <55 mm. (Class of recommendation I, level of evidence B) (Haan et al., 2004; Enriquez-Sarano et al., 1994)

Surgery is indicated in asymptomatic patients with LV dysfunction (LVESD ≥45 mm and/or LVEF ≤60%). (Class of recommendation I, level of evidence C)

Surgery should be considered in asymptomatic patients with preserved LV function and new onset of atrial fibrillation or pulmonary hypertension (systolic pulmonary pressure at rest >50 mmHg). (Class of recommendation IIa, level of evidence C)

Surgery should be considered in asymptomatic patients with preserved LV function, high likelihood of durable repair, low surgical risk and flail leaflet and LVESD ≥40 mm. (Class of recommendation IIa, level of evidence C)

Surgery should be considered in patients with severe LV dysfunction (LVEF <30% and/or LVESD >55 mm) refractory to medical therapy with high likelihood of durable repair and low comorbidity. (Class of recommendation IIa, level of evidence C)

Surgery may be considered in patients with severe LV dysfunction (LVEF <30% and/or LVESD >55 mm) refractory to medical therapy with low likelihood of durable repair and low comorbidity. (Class of recommendation IIb, level of evidence C)

Surgery may be considered in asymptomatic patients with preserved LV function, high likelihood of durable repair, low surgical risk, and:

- Left atrial dilatation (volume index ≥60 ml/m^2 BSA) and sinus rhythm, or
- Pulmonary hypertension on exercise (systolic pulmonary artery pressure [SPAP] ≥60 mmHg at exercise)

(Class of recommendation IIb, level of evidence C)

Secondary Mitral Regurgitation

Indications for Mitral Valve Surgery in Chronic Secondary Mitral Regurgitation

Surgery is indicated in patients with severe MR* undergoing CABG, and LVEF >30%. (Class of recommendation I, level of evidence C)

Surgery should be considered in patients with moderate MR undergoing CABG.** (Class of recommendation IIa, level of evidence C)

Surgery should be considered in symptomatic patients with severe MR, LVEF <30%, option for revascularization, and evidence of viability. (Class of recommendation IIa, level of evidence C)

Surgery may be considered in patients with severe MR, LVEF >30%, who remain symptomatic despite optimal medical management (including cardiac resynchronization [CRT] if indicated) and have low comorbidity, when revascularization is not indicated. (Class of recommendation IIb, level of evidence C)

*The thresholds for severity (effective regurgitant orifice area [EROA] ≥20 mm^2; R Vol >30 ml) differ from that of primary MR and are based on the prognostic value of these thresholds to predict poor outcome (see Table 5 in the original guideline document).

**When exercise echocardiography is feasible, the development of dyspnoea and increased severity of MR associated with pulmonary hypertension are further incentives to surgery.

Mitral Stenosis (MS)

Indications for Intervention

Indications for Percutaneous Mitral Commissurotomy (PMC) in Mitral Stenosis with Valve Area ≤1.5 cm^2

PMC is indicated in symptomatic patients with favourable characteristics.* (Class of recommendation I, level of evidence B) (Bouleti et al., 2012; Cruz-Gonzalez et al., 2009).

PMC is indicated in symptomatic patients with contraindication or high risk for surgery. (Class of recommendation I, level of evidence C)

PMC should be considered as initial treatment in symptomatic patients with unfavourable anatomy but without unfavourable clinical characteristics.* (Class of recommendation IIa, level of evidence C)

PMC should be considered in asymptomatic patients without unfavourable characteristics* and

- High thromboembolic risk (previous history of embolism, dense spontaneous contrast in the left atrium, recent or paroxysmal atrial fibrillation) and/or
- High risk of haemodynamic decompensation (systolic pulmonary pressure >50 mmHg at rest, need for major non-cardiac surgery, desire for pregnancy)

(Class of recommendation IIa, level of evidence C)

*Unfavourable characteristics for percutaneous mitral commissurotomy can be defined by the presence of several of the following characteristics:

> Clinical characteristics: old age, history of commissurotomy, New York Heart Association (NYHA) class IV, permanent atrial fibrillation, severe pulmonary hypertension.
> Anatomical characteristics: echo score >8, Cormier score 3 (calcification of mitral valve of any extent, as assessed by fluoroscopy), very small mitral valve area, severe tricuspid regurgitation.

Tricuspid Regurgitation (TR)

Indications for Tricuspid Valve Surgery

Surgery is indicated in symptomatic patients with severe tricuspid stenosis (TS).* (Class of recommendation I, level of evidence C)

Surgery is indicated in patients with severe TS undergoing left-sided valve intervention.** (Class of recommendation I, level of evidence C)

Surgery is indicated in patients with severe primary or secondary TR undergoing left-sided valve surgery. (Class of recommendation I, level of evidence C)

Surgery is indicated in symptomatic patients with severe isolated primary TR without severe right ventricular dysfunction. (Class of recommendation I, level of evidence C)

Surgery should be considered in patients with moderate primary TR undergoing left-sided valve surgery. (Class of recommendation IIa, level of evidence C)

Surgery should be considered in patients with mild or moderate secondary TR with dilated annulus (≥40 mm or >21 mm/m^2) undergoing left-sided valve surgery. (Class of recommendation IIa, level of evidence C)

Surgery should be considered in asymptomatic or mildly symptomatic patients with severe isolated primary TR and progressive right ventricular dilatation or deterioration of right ventricular function. (Class of recommendation IIa, level of evidence C)

After left-sided valve surgery, surgery should be considered in patients with severe TR who are symptomatic or have progressive right ventricular dilatation/dysfunction, *in the absence* of left-sided valve dysfunction, severe right or left ventricular dysfunction, and severe pulmonary vascular disease. (Class of recommendation IIa, level of evidence C)

*Percutaneous balloon valvuloplasty can be attempted as a first approach if TS is isolated.

**Percutaneous balloon valvuloplasty can be attempted if PMC can be performed on the mitral valve.

Prosthetic Valves

Choice of Prosthetic Valves

Choice of the Aortic/Mitral Prosthesis. In Favour of a Mechanical Prosthesis

A mechanical prosthesis is recommended according to the desire of the informed patient and if there are no contraindications for long-term

anticoagulation.* (Class of recommendation I, level of evidence C)

A mechanical prosthesis is recommended in patients at risk of accelerated structural valve deterioration.** (Class of recommendation I, level of evidence C)

A mechanical prosthesis is recommended in patients already on anticoagulation as a result of having a mechanical prosthesis in another valve position. (Class of recommendation I, level of evidence C)

A mechanical prosthesis should be considered in patients aged <60 years for prostheses in the aortic position and <65 years for prostheses in the mitral position.† (Class of recommendation IIa, level of evidence C)

A mechanical prosthesis should be considered in patients with a reasonable life expectancy,‡ for whom future redo valve surgery would be at high risk. (Class of recommendation IIa, level of evidence C)

A mechanical prosthesis may be considered in patients already on long-term anticoagulation due to high risk of thromboembolism.§ (Class of recommendation IIb, level of evidence C)

*Increased bleeding risk because of comorbidities, compliance concerns, geographic, lifestyle and occupational conditions.

**Young age (<40 years), hyperparathyroidism.

†In patients aged 60–65 years who should receive an aortic prosthesis, and those between 65–70 years in the case of mitral prosthesis, both valves are acceptable and the choice requires careful analysis of other factors than age.

‡Life expectancy should be estimated >10 years, according to age, gender, comorbidities, and country-specific life expectancy.

§Risk factors for thromboembolism are atrial fibrillation, previous thromboembolism, hypercoagulable state, severe left ventricular systolic dysfunction.

Choice of the Aortic/Mitral Prosthesis. In Favour of a Bioprosthesis

A bioprosthesis is recommended according to the desire of the informed patient. (Class of recommendation I, level of evidence C)

A bioprosthesis is recommended when good quality anticoagulation is unlikely (compliance problems, not readily available) or contraindicated because of high bleeding risk (prior major bleed, comorbidities, unwillingness, compliance problems, lifestyle, occupation). (Class of recommendation I, level of evidence C)

A bioprosthesis is recommended for reoperation for mechanical valve thrombosis despite good long-term anticoagulant control. (Class of recommendation I, level of evidence C)

A bioprosthesis should be considered in patients for whom future redo valve surgery would be at low risk. (Class of recommendation IIa, level of evidence C)

A bioprosthesis should be considered in young women contemplating pregnancy. (Class of recommendation IIa, level of evidence C)

A bioprosthesis should be considered in patients aged >65 years for prosthesis in aortic position or >70 years in mitral position, or those with life expectancy* lower than the presumed durability of the bioprosthesis.** (Class of recommendation IIa, level of evidence C)

*Life expectancy should be estimated according to age, gender, comorbidities, and country-specific life expectancy.

**In patients aged 60–65 years who should receive an aortic prosthesis and those 65–70 years in the case of mitral prosthesis, both valves are acceptable and the choice requires careful analysis of factors other than age.

Management after Valve Replacement

Indications for Antithrombotic Therapy after Valvular Surgery

Oral anticoagulation is recommended lifelong for all patients with a mechanical prosthesis. (Class of recommendation I, level of evidence B) (Cannegieter, Rosendaal, & BriÑ't, 1994).

Oral anticoagulation is recommended lifelong for patients with bioprostheses who have other indications for anticoagulation.* (Class of recommendation I, level of evidence C)

The addition of low-dose aspirin should be considered in patients with a mechanical prosthesis and concomitant atherosclerotic disease. (Class of recommendation IIa, level of evidence C)

The addition of low-dose aspirin should be considered in patients with a mechanical prosthesis after thromboembolism despite adequate

international normalized ratio (INR). (Class of recommendation IIa, level of evidence C)

Oral anticoagulation should be considered for the first three months after implantation of a mitral- or tricuspid bioprosthesis. (Class of recommendation IIa, level of evidence C)

Oral anticoagulation should be considered for the first three months after mitral valve repair. (Class of recommendation IIa, level of evidence C)

Low-dose aspirin should be considered for the first three months after implantation of an aortic bioprosthesis. (Class of recommendation IIa, level of evidence C)

Oral anticoagulation may be considered for the first three months after implantation of an aortic bioprosthesis. (Class of recommendation IIb, level of evidence C)

*Atrial fibrillation, venous thromboembolism, hypercoagulable state, or with a lesser degree of evidence, severely impaired left ventricular dysfunction (ejection fraction <35%).

Definitions:

Levels of Evidence

Level of Evidence A	Data derived from multiple randomized clinical trials or meta-analyses.
Level of Evidence B	Data derived from a single randomized clinical trial or large non-randomized studies.
Level of Evidence C	Consensus of opinion of the experts and/or small studies, retrospective studies, registries.

Classes of Recommendations

Classes of Recommendations	Definition	Suggested Wording to Use
Class I	Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective.	Is recommended/is indicated
Class II	Conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the given treatment or procedure.	
Class IIa	*Weight of evidence/opinion is in favour of usefulness/efficacy.*	Should be considered
Class IIb	*Usefulness/efficacy is less well established by evidence/opinion.*	May be considered
Class III	Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful.	Is not recommended

Clinical Algorithm(s)

Algorithms are provided in the original guideline document for the following:

- Management of aortic regurgitation
- Management of severe aortic stenosis
- Management of severe chronic primary mitral regurgitation
- Management of clinically significant mitral stenosis
- Management of left-sided obstructive prosthetic thrombosis
- Management of left-sided non-obstructive prosthetic thrombosis
- Management of severe aortic stenosis and elective non-cardiac surgery according to patient characteristics and the type of surgery

Scope

Disease/Condition(s)

Valvular heart disease, including:

- Aortic regurgitation
- Aortic stenosis
- Mitral regurgitation (primary and secondary)
- Mitral stenosis
- Tricuspid stenosis
- Tricuspid regurgitation
- Combined and multiple valve disease

Other Disease/Condition(s) Addressed

- Coronary artery disease
- Marfan syndrome
- Pulmonary hypertension
- Systolic left ventricular dysfunction

Guideline Category

Diagnosis

Evaluation

Management

Risk Assessment

Treatment

Clinical Specialty

Cardiology

Geriatrics

Internal Medicine

Obstetrics and Gynecology

Surgery

Thoracic Surgery

Intended Users

Physicians

Guideline Objective(s)

- To assist physicians in selecting the best possible management strategies for the individual patient with a given condition, taking into account the impact on outcome, as well as the risk-benefit ratio of a particular diagnostic or therapeutic means
- To update the 2007 European Society of Cardiology guidelines on management of valvular heart disease

Target Population

Patients with acquired valvular heart disease, including pregnant women with valvular heart disease

Note: The guidelines do not deal with endocarditis and congenital valve disease, including pulmonary valve disease.

Interventions and Practices Considered

1. Coronary angiography
2. Cardiac catheterization
3. Surgery
    - Aortic and mitral valve replacement or valve repair
    - Percutaneous balloon valvuloplasty
    - Percutaneous mitral valve repair using the edge to edge technique
    - Percutaneous mitral commissurotomy (PMC)
    - Transcatheter aortic valve implantation (TAVI)
    - Tricuspid valve surgery
4. Choice of valve prosthesis (mechanical valve versus bioprosthesis)
5. Serial testing (scheduled follow-up)
6. Management of special populations
7. Management after valve replacement: antithrombotic management, including antiplatelet drugs and interruption of anticoagulant therapy

Note: See the original guideline document for other interventions that were considered but for which no specific recommendations were made.

Major Outcomes Considered

- Utility of diagnostic tests
- Operative mortality
- Survival
- Preservation of left ventricular function
- Long-term morbidity
- Probability of durable valve repair

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

A literature review was performed using PubMed, EMBASE, Medline, Scopus, and Cochrane databases, focusing on the studies published over the 10 previous years. Specific search terms used were: valve disease, valve surgery, percutaneous valve intervention, aortic stenosis, mitral regurgitation, mitral stenosis, aortic regurgitation, tricuspid stenosis, tricuspid regurgitation.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Levels of Evidence

Level of Evidence A	Data derived from multiple randomized clinical trials or meta-analyses.
Level of Evidence B	Data derived from a single randomized clinical trial or large non-randomized studies.
Level of Evidence C	Consensus of opinion of the experts and/or small studies, retrospective studies, registries.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

A critical evaluation of diagnostic and therapeutic procedures was performed, including assessment of the risk–benefit ratio. Estimates of expected health outcomes for larger populations were included, where data exist. The levels of evidence and the strengths of recommendation of particular treatment options were weighed and graded according to predefined scales (see the "Rating Scheme for the Strength of the Evidence" and the "Rating Scheme for the Strength of the Recommendations" fields).

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Members of this Task Force were selected by the European Society of Cardiology (ESC) and European Association for Cardio-Thoracic Surgery (EACTS) to represent professionals involved with the medical care of patients with this pathology. Selected experts in the field undertook a comprehensive review of the published evidence for diagnosis, management and/or prevention of a given condition, according to ESC Committee for Practice Guidelines (CPG) and EACTS policy.

Rating Scheme for the Strength of the Recommendations

Classes of Recommendations

Classes of Recommendations	Definition	Suggested Wording to Use
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Class III	Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful.	Is not recommended

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The European Society of Cardiology Committee/European Association for Cardio-Thoracic Surgery (ESC/EACTS) Guidelines undergo extensive review by the Clinical Guidelines Committee (CPG), the Clinical Guidelines Committee of EACTS and external experts. After appropriate revisions, it is approved by all the experts involved in the Task Force. The finalized document is approved by the CPG for publication in the *European Heart Journal* and the *European Journal of Cardio-Thoracic Surgery*.

Evidence Supporting the Recommendations

References Supporting the Recommendations

Bouleti C, Iung B, Laouenan C, Himbert D, Brochet E, Messika-Zeitoun D, Detaint D, Garbarz E, Cormier B, Michel PL, Mentre F, Vahanian A. Late results of percutaneous mitral commissurotomy up to 20 years: development and validation of a risk score predicting late functional results from a series of 912 patients. Circulation. 2012 May 1;125(17):2119-27. PubMed

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Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Improved management strategies for the individual patient suffering from valvular heart disease, taking into account the impact on outcome and also the risk-benefit ratio of a particular diagnostic or therapeutic procedure

Potential Harms

- Risks of valvular surgery, including perioperative mortality and postoperative complications (e.g., thromboses, embolism)
- Bleeding complications associated with anticoagulant therapy
- Maternal mortality is estimated at between 1% and 4% in women with mechanical valves. These patients should be informed of the risks and constraints due to anticoagulant therapy if pregnancy occurs. During the first trimester, in choosing between vitamin K antagonists, unfractionated heparin, and low-molecular-weight heparin, the respective maternal and foetal risks should be weighed up carefully. Vitamin K antagonists are favoured during the second and third trimester until the 36th week, when they should be replaced by heparin.

Contraindications

Contraindications

- Exercise testing is contraindicated in symptomatic patients with aortic stenosis (AS).
- Low-molecular-weight heparins are contraindicated in cases of severe renal failure.
- Anticoagulation is contraindicated in patients with a high bleeding risk (prior major bleed; comorbidities; unwillingness; compliance problems; lifestyle; occupation).
- Contraindications to percutaneous mitral commissurotomy include:

    - Mitral valve area >1.5 cm^2
    - Left atrial thrombus
    - More than mild mitral regurgitation
    - Severe or bicommissural calcification
    - Absence of commissural fusion
    - Severe concomitant aortic valve disease or severe combined tricuspid stenosis and regurgitation
    - Concomitant coronary artery disease requiring bypass surgery
- Contraindications for transcatheter aortic valve implantation (TAVI) include:
    - Absolute contraindications:
        - Absence of a 'heart team' and no cardiac surgery on the site
        - Appropriateness of TAVI, as an alternative to aortic valve replacement (AVR), not confirmed by a 'heart team'
        - Estimated life expectancy <1 year
        - Improvement of quality of life by TAVI unlikely because of comorbidities
        - Severe primary associated disease of other valves with major contribution to the patient's symptoms, that can be treated only by surgery
        - Inadequate annulus size (<18 mm, >29 mm) (contraindication when using the current devices)
        - Thrombus in the left ventricle
        - Active endocarditis
        - Elevated risk of coronary ostium obstruction (asymmetric valve calcification, short distance between annulus and coronary ostium, small aortic sinuses)
        - Plaques with mobile thrombi in the ascending aorta, or arch
        - For transfemoral/subclavian approach: inadequate vascular access (vessel size, calcification, tortuosity)
    - Relative contraindications:
        - Bicuspid or non-calcified valves
        - Untreated coronary artery disease requiring revascularization
        - Haemodynamic instability
        - Left ventricular ejection fraction <20%
        - For transapical approach: severe pulmonary disease, left ventricular apex not accessible

Qualifying Statements

Qualifying Statements

- The European Society of Cardiology (ESC)/European Association for Cardio-Thoracic Surgery (EACTS) Guidelines represent the views of the ESC and the EACTS and were arrived at after careful consideration of the available evidence at the time they were written. Health professionals are encouraged to take them fully into account when exercising their clinical judgment. The guidelines do not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patients, in consultation with that patient, and where appropriate and necessary, the patient's guardian or carer. It is also the health professional's responsibility to verify the rules and regulations applicable to drugs and devices at the time of prescription.
- The committee emphasizes that many factors ultimately determine the most appropriate treatment in individual patients within a given community. These factors include availability of diagnostic equipment, the expertise of cardiologists and surgeons, especially in the field of valve repair and percutaneous intervention, and, notably, the wishes of well-informed patients. Furthermore, due to the lack of evidence-based data in the field of valvular heart disease, most recommendations are largely the result of expert consensus opinion. Therefore, deviations from these guidelines may be appropriate in certain clinical circumstances.
- Guidelines are not substitutes for, but complements to, textbooks and cover the ESC Core Curriculum topics. Guidelines and recommendations should help physicians to make decisions in their daily practice. However, the final decisions concerning an individual patient must be made by the responsible physician(s).

Implementation of the Guideline

Description of Implementation Strategy

Description of Implementation Strategy

After publication, dissemination of the message is of paramount importance. Pocket-sized versions and personal digital assistant (PDA) downloadable versions are useful at the point of care. Some surveys have shown that the intended end-users are sometimes unaware of the existence of guidelines, or simply do not translate them into practice, so this is why implementation programmes for new guidelines form an important component of the dissemination of knowledge. Meetings are organized by the European Society of Cardiology (ESC) and European Association for Cardio-Thoracic Surgery (EACTS) and directed towards their member National Societies and key opinion-leaders in Europe. Implementation meetings can also be undertaken at national levels, once the guidelines have been endorsed by the ESC and EACTS member societies and translated into the national language. Implementation programmes are needed because it has been shown that the outcome of disease may be favourably influenced by the thorough application of clinical recommendations.

Thus the task of writing these Guidelines covers not only the integration of the most recent research, but also the creation of educational tools and implementation programmes for the recommendations. The loop between clinical research, writing of guidelines and implementing them into clinical practice can only then be completed if surveys and registries are performed to verify that real-life daily practice is in keeping with what is recommended in the guidelines. Such surveys and registries also make it possible to evaluate the impact of implementation of the guidelines on patient outcomes.

Implementation Tools

Clinical Algorithm

Foreign Language Translations

Mobile Device Resources

Pocket Guide/Reference Cards

Quick Reference Guides/Physician Guides

Slide Presentation

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (, European Association for Cardio-Thoracic Surgery (EACTS), Vahanian A, Alfieri O, Andreotti F, Antunes MJ, Baron-Esquivias G, Baumgartner H, Borger MA, Carrel TP, De Bonis M, Evangelista A, Falk V, Iung B, Lancellotti P, Pierard L, Price S, Schafers HJ, Schuler G, Stepinska J, Swedberg K, Takkenberg J, Von Oppell UO, Windecker S, Zamorano JL, Zembala M. Guidelines on the management of valvular heart disease (version 2012). Eur Heart J. 2012 Oct;33(19):2451-96. PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

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Guideline Developer(s)

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Guideline Endorser(s)

Association of Cardiologists of Kazakhstan - Professional Association

Belorussian Scientific Society of Cardiologists - Medical Specialty Society

Cardiology Society of Serbia - Medical Specialty Society

Croatian Cardiac Society - Medical Specialty Society

Czech Society of Cardiology - Medical Specialty Society

Danish Society of Cardiology - Medical Specialty Society

French Society of Cardiology - Medical Specialty Society

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Slovak Society of Cardiology - Medical Specialty Society

Society of Cardiology of the Russian Federation - Medical Specialty Society

Spanish Society of Cardiology - Medical Specialty Society

Turkish Society of Cardiology - Medical Specialty Society

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Vahanian A, Baumgartner H, Bax J, Butchart E, Dion R, Filippatos G, Flachskampf F, Hall R, Iung B, Kasprzak J, Nataf P, Tornos P, Torracca L, Wenink A, Priori SG, Blanc JJ, Budaj A, Camm J, Dean V, Deckers J, Dickstein K, Lekakis J, McGregor K, Metra M, Morais J, Osterspey A, Tamargo J, Zamorano JL, Zamorano JL, Angelini A, Antunes M, Fernandez MA, Gohlke-Baerwolf C, Habib G, McMurray J, Otto C, Pierard L, Pomar JL, Prendergast B, Rosenhek R, Uva MS, Tamargo J. Guidelines on the management of valvular heart disease: The Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology. Eur Heart J 2007 Jan;28(2):230-68.

Guideline Availability

Electronic copies: Available from the European Society of Cardiology (ESC) Web site . Also available in Polish from the ESC Web site.

Print copies: Available from Oxford University Press, Great Clarendon Street, Oxford, OX2 6DP, UK, Tel: +44 (0) 1865 353263, Fax: +44 (0) 1865 353774, Web site: http://www.eurheartj.oxfordjournals.org/ .

Availability of Companion Documents

The following are available:

- ESC/EACTS guidelines on the management of valvular heart disease (version 2012). Essential messages. 2012. 8 p. Electronic copies: Available from the European Society of Cardiology (ESC) Web site .
- Valvular heart disease. Pocket guidelines. European Society of Cardiology; 2012. Available for order from the ESC Web site . Also available for mobile download from the ESC Web site .
- Valvular heart disease. Educational slide set. European Society of Cardiology; 2012. Electronic copies: Available to registered users from the ESC Web site .
- Summary of valvular heart disease. 2012. 2 p. Electronic copies: Available to registered users from the ESC Web site .

Print copies: Available from Oxford University Press, Great Clarendon Street, Oxford, OX2 6DP, UK, Tel: +44 (0) 1865 353263, Fax: +44 (0) 1865 353774, Web site: http://www.eurheartj.oxfordjournals.org/ .

Additionally, continuing medical education (CME) credit is available online at the ESC Web site .

Patient Resources

None available

NGC Status

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